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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,881	01/11/1999	THAI D. NGUYEN	07425.0057	7578
28381	7590	11/19/2004	EXAMINER	
ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/227,881

Applicant(s)

NGUYEN ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 144-174 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 144, 146-155, 157-166 and 168-174 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 145, 156, and 167, and subject matter of claims 145-154, 156-165, and 167-174 drawn to complements of SEQ ID NO: 34 .

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed September 3, 2004 and September 23, 2004 have been considered. Rejections and/or objections not reiterated from the previous office action mailed June 3, 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed June 18, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference statements to parent applications to which priority is claimed, submitted on June 18, 2001.

Applicants amended the first paragraph of the specification on June 18, 2001 to recite a CIP priority statement to U.S. Application Number 08/938,669, and U.S. Application Number 08/791,154. However, the accompanying this claim to priority was a statement that incorporated both of said applications by reference into the instant specification. While the claim to priority is considered proper, the incorporations by reference are not considered proper. From M.P.E.P.

201.06(c):

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A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See *Dart Indus. v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980).

Applicant is required to cancel the new matter in the reply to this Office Action.

Election/Restrictions

Newly submitted subject matter drawn to complement of a fragment of SEQ ID NO: 34, which appears in claims 145-154, 156-165, and 167-174, is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention reciting fragments of the sense strand of SEQ ID NO: 34 is considered to be unrelated to the invention reciting fragments of the complementary strand. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the claimed subject matter drawn to fragments of the complement (antisense) strand of SEQ ID NO: 34 are considered to constitute a different sequence when compared to the fragments of the sense strand of SEQ ID NO: 34, because the complement has a materially different structure (i.e. sequence), which are not disclosed as useful together. Furthermore, the antisense fragments have a different function from the regulatory fragments of the sense strand in

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that they typically serve as probes or primers or antisense inhibitors. Accordingly, the fragments of the sense strand and fragments of the antisense strand have different modes of operation, different effects, and different functions. Finally, a different search is required because the two strands have different sequences. Because these inventions are distinct for the reasons given above and because these sequences do not overlap, are not co-extensive and are drawn to divergent subject matter, a search of these different inventions is considered a serious burden, and restriction for examination purposes as thus indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 145, 156, and 167, which exclusively recite complements, and the subject matter of claims 145-154, 156-165, and 167-174 as they are drawn to complements are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 144, 146-155, 157-166, and 168-174 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The invention of the above claims is drawn to fragments from about 15 to 250 nucleotides of SEQ ID NO: 34, or fragments from about 15 to 250 nucleotides of nucleotides 1 through 5271 of SEQ ID NO: 3, which applicants have indicated is identical to SEQ ID NO: 34, and to nucleic acids comprising the whole of SEQ ID NO: 34, and to vectors and cells containing same. These claims have been amended to withdraw functional language that is considered to describe these fragments as comprising regulatory regions. It is the cancellation of such functional language that necessitates the instant rejection.

The specification teaches that a number of consensus sequences for regulatory response elements such as progesterone, glucocorticoid, shear stress motif, p53, and epidermal growth factor among others are found in SEQ ID NO: 1, which is the TIGR promotor region, which presumably is contained within the instant SEQ ID NO: 34. This presumption is based on the teachings of the specification at page 9 (last paragraph) that SEQ ID NO: 34 is the upstream region of the TIGR gene before the transcription start site.

Applicants' most recent amendment deleted functional language from the independent claims that required that the instantly claimed fragments comprise regulatory regions. However, applicants have disclosed only those fragments that have regulatory function. Thus, while applicants have provided written description for a limited number of species of fragments of SEQ ID NO: 34 comprising regulatory function, the amendment deleting such functional language claims improperly broadens the scope of the claims because no other types of fragments have been described. Therefore, the attempt to delete the functional language of the

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fragments of SEQ ID NO: 34 is considered to constitute new matter, because one of skill would not have envisioned any fragments beyond those having the regulatory function of SEQ ID NO: 34 so disclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 144, 146-149, 151-153, 155, 157-160, and 162-164 are rejected under 35

U.S.C. 102(b) as being anticipated by Georges *et al.* (WO 92/13102). The Georges reference is a over 550 pages long, most of which consists of a lengthy sequence listing. The entire specification, claims, all drawings, and relevant page of sequence listing has been included herewith, while only the remainder of the sequence listing, which is not considered relevant to the instant rejection, has been excluded. Should applicants desire to see the remaining sequence listing, this will be provided upon request. In any case, applicants should be aware that such a request would not serve to restart the period for response to the instant action.

The claims above are drawn to nucleic acids which comprise a fragment of SEQ ID NO: 34, wherein the fragment is 15 to 250 nucleotides long, or to nucleic acids which comprise a fragment of nucleotides 1 through 5271 of SEQ ID NO: 3 (wherein nucleotides 1 through 5271 of SEQ ID NO: 3 is alleged by applicants to be identical to SEQ ID NO: 34), wherein the fragment is 15 to 250 nucleotides long, wherein said nucleic acids are optionally contained in

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vectors or cells. The invention is also drawn to nucleic acids comprising the full length of SEQ ID NO: 34, and to cells and vectors thereof.

Georges *et al.* teaches SEQ ID NO: 308, which is a polymorphic DNA marker, which comprises a fragment corresponding to nucleotides 4997-5023 of the instant SEQ ID NO: 34, and thus is a fragment of SEQ ID NO: 34, or a fragment of nucleotides 1 through 5271 of SEQ ID NO: 3 between 15 to 250 nucleotides long, Georges also teaches said fragment in cells and vectors thereof. Therefore, all claim limitations are considered to be taught by Georges, and the invention of the above claims is considered to be anticipated.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 144, 146-155, 157-166, and 168-174 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27, 29, 43 and 45 of U.S. Patent No. 6,171,788. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to fragments between 15

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and 250 nucleotides of SEQ ID NO: 34 that may optionally be in vectors or cells, while the claims of U. S. Patent Number 6,171,788 are drawn to nucleic acids comprising SEQ ID NOS: 1 and 3, both of which contain the instant SEQ ID NO: 34, wherein the patented sequences are taught in cells and vectors. U. S. Patent Number 6,171,788 is also drawn to methods of diagnosing glaucoma, wherein a TIGR promoter sequence comprising fragments between 15 and 250 nucleotides of SEQ ID NO: 1 or 3. Since both SEQ ID NOS: 1 and 3 of the patent are long sequences that contain SEQ ID NO: 34, and because the instant claims recite the open “comprising” language of the nucleic acid of SEQ ID NO: 34, the patented claims are considered to embrace the instant claims.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

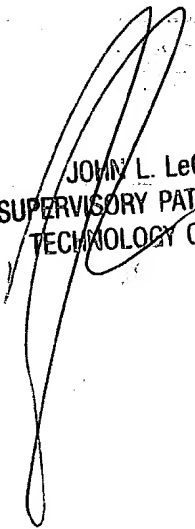
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(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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